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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,152	11/12/2003	Steven T. Luebbers	7016US01	7581

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ROSS PRODUCTS DIVISION OF ABBOTT LABORATORIES
DEPARTMENT 108140-DS/1
625 CLEVELAND AVENUE
COLUMBUS, OH 43215-1724

EXAMINER	
PRATT, HELEN F	
ART UNIT	**PAPER NUMBER**
1761	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/706,152	LUEBBERS, STEVEN T.	
	Examiner	Art Unit	
	Helen F. Pratt	1761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-12,14-22 and 24-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-12,14-22 and 24-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-12, 14-22, 24-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Girsh (5,204,134) or Cope et al. (5,480,872) or Hill et al. (5,382,439) in view of Lien et al. (US 2004/0062849).

Girsh discloses a process of making a hypoallergenic milk by sterilizing a liquid nutritional formula aseptically containing Vitamin D and hydrolyzed protein. The short chain polypeptides are obtained by appropriate hydrolysis. The short chain polypeptide has a molecular weight of from 1 to 5 kDa (abstract and col. 5, lines 15-30, col. 9, lines 5-15, col. 10, lines 15-18). Applicants' specification on page 11, 1st paragraph, discloses that hydrolyzed proteins can be various weights, e. g. 2000 to 5000 Daltons. It is not known what molecular weight applicants' proteins would have been if hydrolyzed to at least 20%. Also, Girsh discloses the use of amino acids and short chain polypeptides derived from hydrolysates (col. 10, lines 25-25). Therefore, absent a showing to the contrary, it is seen that Girsh discloses protein hydrolysates as disclosed above which have the claimed degree of hydrolyzation and it would have been obvious to use such with vitamin D in an especially packaged process in aseptic containers.

Cope discloses that it is known to use soy protein hydrolysates having a DH of from 14 to 17 and in the use of particles having a molecular weight of from 1,500-500 Daltons in a composition containing vitamin D3 (abstract, col. 15, lines 5-44, in particularly lines 5-10). Claim 1 differs from the reference in having a DH of at least 20%. However, the reference discloses about 14-17 DH and the claim says "at least about 20%". Nothing is seen at this time that a DH of 17 would not have produced a product similar or the same as applicants. Cope also discloses that aseptic methods can be used to treat the composition (col. 16, lines 54-60). Therefore, it would have been obvious to use a hydrolyzed protein at near the claimed range and vitamin D in a process for aseptic composition.

Hill et al. disclose a process of improving the stability of V-D in liquid nutritional products using hydrolyzed protein and vitamin C (abstract). The composition is heat treated aseptically (col. 3, lines 15-22). Claim 1 differs from the reference in the use of hydrolyzed protein to the claimed degree. Nothing is seen that the protein is not hydrolyzed to the claimed degree especially as even amino acids are used (col. 4, lines 29-34). Therefore, it would have been obvious to use hydrolyzed protein and amino acids in the claimed process as shown by Hill.

The above references do not show the exact degree of protein hydrolysis. However, Lien et al. disclose that it is known to use isolated soy protein with a DH of from 5-20%. Therefore, it would have been obvious to use a known DH of protein in the processes of the above references in order to improve the digestibility of the protein (abstract and para. 0011, 0035).

The independent claims have been amended to require plastic containers. Nothing new is seen as in claims 1 and 3, in the use of plastic packages and resealable unidose packages, which are commonly in use as in, milk containers and baby formula containers. Vitamin D containing milk is routinely put in opaque plastic contains, which are not further heat treated, due to the degradation from light. Applicants' specification on page 3, lines 16-27 discloses that various baby formulas are aseptically packaged. Therefore, it would have been obvious to use known types of packages in the claimed process.

Claims 4 and 5 further require more hydrolysis of the protein. However, as it is known to hydrolyze protein, it would have been obvious to hydrolyze to whatever degree was required depending on the purpose of the product. Cope discloses the use of vitamin C in the composition (col. 14, lines 48-51) and Girsh in col. 7, lines 5-10.

Claim 7 further requires that the V-D have a degradation rate reduction from 20-40% and claim 8 from 25-35%. However, nothing is seen that the process of the above references would not have produced such a degradation rate. Therefore, it would have been obvious to produce degradation rates within or near the claimed range as shown by the references.

Girsh discloses a liquid infant formula as in claim 9 (col. 10, lines 30-35).

No further heat sterilization is seen in the above references as in claim 10.

Certainly, Girsh discloses as in claim 11 that the formula is free from intact proteins, as his process uses amino acid and polypeptides (col. 14, lines 14-16).

The limitations of claims 12, 14-22, 24-30 have been disclosed above and are obvious for those reasons.

ARGUMENTS

Applicant's arguments filed 11-29-06 have been fully considered but they are not persuasive. Applicants argue that vitamin D showed significant improved stability when packaged in plastic containers. However, these citations are to aseptic packages in dark containers and plastic is not separately evaluated as to plastic containers.

Applicants disclose on page 8, lines 23-30, of the specification that various types of containers can be used, but preferably plastic. Therefore, since the data on Table 4 is to dark conditions with no particular type of container, it is seen that the data does not specifically support the use of plastic.

In addition, plastic containers are commonly used to store milk so that the vitamin D and A will not be degraded.

Girsh discloses aseptic packaging in containers and Applicants' specification discloses various containers can be used, but no data is given to support the limitation that plastic containers give better results than the other type of containers.

Applicant argues that Girsh teaches away from vitamin D stability. However, applicants' claims do not exclude the use of water-soluble vitamin D or cysteine.

Applicants argue as to Hill who does treat aseptically particularly using HTST and excludes retort and terminal sterilization (col. 3, lines 20-24). HTST indicates sterilization, not just a preliminary heat treatment. Surely if HTST is used there is no need for retorting, which indicates aseptic packaging was used.

Even if Lien and Cope fail to teach aseptic plastic packaging, the use of plastic containers is not seen as being critical. Nothing is seen in the tests that they were to plastic aseptic packaging. Therefore, the other types of packaging could be used as cited in the specification with the same results making the use of plastic containers not critical.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen F. Pratt whose telephone number is 571-272-1404. The examiner can normally be reached on Monday to Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Milton Cano, can be reached on 571-272-1398. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hp 1-18-07

H. Pratt

HELEN PRATT
PRIMARY EXAMINER